EXHIBIT A

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL No. 1456 Civil Action No. 01-12257-PBS
THIS DOCUMENT RELATES TO:	)	Hon. Patti Saris
United States of America ex rel. Ven-a-Care of the Florida Keys, Inc., v. Abbott Laboratories, Inc., CIVIL ACTION NO. 06-11337-PBS	)	(Original Complaint Filed in the Southern District of Florida, Case No. 06-21303-CIV-GOLD/TURNOFF)

THE UNITED STATES' FIRST AMENDED COMPLAINT

The United States brings this fraud action against Abbott Laboratories, Inc. ("Abbott") to recover losses sustained by the Medicare and Medicaid programs. Over the course of several years, Abbott reported inflated pharmaceutical prices that it knew Medicare and Medicaid relied upon to set reimbursement rates for Abbott's pharmaceutical products. Abbott's actual sales prices for its pharmaceutical products were far less than the prices reported by Abbott. By knowingly reporting inflated prices – often 1000% higher than Abbott's actual prices – Abbott ensured its customers received inflated reimbursement and profits from Medicare and Medicaid. Abbott then used the public fisc as a marketing tool, actively promoting government-funded "spreads" between (1) its fraudulently inflated prices and (2) its actual sales prices as an inducement to its customers. In addition, Abbott operated its own home infusion pharmacies and entered into profit-sharing partnerships with health care providers that allowed Abbott to directly profit off Abbott's manipulation of third party reimbursements for its drugs. These efforts allowed Abbott to increase its profits by boosting sales for its drugs.

I. NATURE OF ACTION

1. The United States brings this action to recover treble damages and civil penalties under the False Claims Act ("FCA"), 31 U.S.C. §§ 3729-33, and to recover damages and other monetary relief under the common law or equitable theories of fraud and unjust enrichment.

2. The United States bases its claims on Abbott having **submitted and** caused the submission of false or fraudulent claims to the United States in violation of 31 U.S.C. § 3729(a)(1), and having made and used false statements to get false or fraudulent claims paid by the United States in violation of 31 U.S.C. § 3729(a)(2).

3. Within the time frames detailed below, Abbott engaged in a fraudulent scheme that caused the Medicare and Medicaid programs to pay excessive reimbursement to Abbott's customers, *e.g.*, pharmacies, physicians, hospitals, home health agencies, nursing homes, home infusion companies, clinics and physicians (hereafter referred to collectively as "Customers"). In furtherance of this scheme, Abbott reported false, fraudulent and inflated drug prices for certain drugs (listed in ¶¶ 30 and 34 below) to several price reporting compendia that the Medicare and Medicaid programs relied upon to set reimbursement rates for Abbott's customers. A chart setting out examples showing the difference between the prices at which Abbott actually sold its drugs and the false prices reported by Abbott is attached hereto as **Exhibit 1**. Abbott knew that the Medicare and Medicaid programs relied on Abbott's reported prices to those compendia to set reimbursement rates for claims submitted for Abbott's drugs. Abbott then sold the drugs for far lower prices, and marketed to existing and potential Customers the government-funded

"spread" between the inflated reimbursement amounts and the actual acquisition costs of the drugs to boost its sales and profits.

4. Abbott knew that its false price reporting and marketing efforts would cause its Customers to submit claims for fraudulently inflated Medicaid and Medicare reimbursement.

5. Abbott's fraudulent scheme to induce Customers to purchase its products by ensuring that federal reimbursement rates for those products would be set at artificially inflated levels violated the FCA, the federal anti-kickback statute, 42 U.S.C. § 1320a-7b(b), common law and numerous state laws.

6. To get fraudulent claims paid by the United States, Abbott also routinely made false statements directly to state Medicaid programs by reporting these same fraudulently inflated prices to the states. These statements violated the FCA, common law and various state laws.

7. The United States timely asserts the causes of action alleged herein based on the filing of relator's complaint in this action.

II. JURISDICTION

8. The United States' original Complaint in this matter was filed on March 16, 2006 in the Southern District of Florida.[1] The case was transferred to Multi-District Litigation ("MDL") No. 1456 on July 27, 2006. The Court has subject matter jurisdiction to entertain this action under 28 U.S.C. §§ 1331 and 1345 and supplemental jurisdiction to entertain the common law and equitable causes of action pursuant to 28 U.S.C. § 1367(a). The Court may exercise

[1] This case originated in the Southern District of Florida as Case No. 06-21303-CIV-GOLD/TURNOFF. The United States understands that this matter will be transferred back to the Southern District of Florida for trial upon the completion of these MDL proceedings.

personal jurisdiction over Abbott pursuant to 31 U.S.C. § 3732(a) because Abbott resides or transacts business in the District of Massachusetts.

III. VENUE

9. Venue is proper in the District of Massachusetts under 31 U.S.C. § 3732 and 28 U.S.C. § 1391(b) and (c) because Abbott resides or transacts business in this District.[2]

IV. PARTIES

10. The United States brings this action on behalf of the Department of Health and Human Services ("HHS") and the Centers for Medicare & Medicaid Services ("CMS") (formerly known as the Health Care Financing Administration), which administer the Medicare and Medicaid programs.

11. Relator Ven-A-Care of the Florida Keys, Inc. ("Ven-A-Care"), is a corporation organized under the laws of Florida, with its principal offices in Key West, Florida. Ven-A-Care is a pharmacy licensed to provide the prescription drugs specified in this Complaint and has been, during the relevant period of this Complaint, a Medicare and Florida Medicaid provider. Ven-A-Care's principal officers and directors have included John M. Lockwood, M.D., Zachary Bentley, Luis Cobo and T. Mark Jones, who are each citizens of the United States and reside in Key West, Florida. The FCA, 31 U.S.C. § 3730(b)(1), provides that private parties may bring a lawsuit on behalf of the United States to recover damages for false claims. Ven-A-Care brought this action against Abbott on behalf of itself and the United States.

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[2] Abbott also resides or transacts business in the Southern District of Florida as well. Thus, venue is also proper in that District.

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12. Defendant Abbott is a corporation organized under the laws of Illinois with its principal offices in Abbott Park, Illinois. At all times material to this civil action, Abbott has transacted business throughout the United States, selling and distributing its drugs, including but not limited to those identified in this Complaint, to purchasers within this District.

V. THE LAW

A. The False Claims Act

13. The FCA provides in pertinent part, that:

> (a) Any person who (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval; (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government
>
> * * *
>
> is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the Government sustains because of the act of that person . . . .
> (b) For purposes of this section, the terms "knowing" and "knowingly" mean that a person, with respect to information (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required.

31 U.S.C. § 3729.

14. Pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, 28 U.S.C. § 2461 (notes), and 64 Fed. Reg. 47099, 47103 (1999), the civil penalties were adjusted to $5,500 to $11,000 for violations occurring on or after September 29, 1999.

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B. The Federal Anti-Kickback Statute

15. Congress first enacted the federal anti-kickback statute, 42 U.S.C. § 1320a-7b(b), in 1972 to protect the integrity of Medicare and Medicaid. Congress strengthened the statute in 1977, and again in 1987, to ensure that kickbacks masquerading as legitimate transactions would not evade its reach. *See* Social Security Amendments of 1972, Pub. L. No. 92-603, §§ 242(b) and (c); 42 U.S.C. § 1320a-7b, Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142; Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93.

16. The anti-kickback statute prohibits any person or entity from making or accepting payment to induce or reward any person for referring, recommending or arranging for federally-funded medical items, including items provided under Medicare and Medicaid. In pertinent part, the statute provides:

> (b) Illegal remuneration
>
> > (1) whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind –
> >
> > > (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
> > >
> > > (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment

> > may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.
>
> (2) whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person --
>
> (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) to purchase, lease, order or arrange for or recommend purchasing, leasing or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b(b). Those who violate the statute also are subject to exclusion from participation in federal health care programs and, effective August 6, 1997, civil monetary penalties of up to $50,000 per violation and up to three times the amount of remuneration paid. 42 U.S.C. § 1320a-7(b)(7) and 42 U.S.C. § 1320a-7a(a)(7).

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VI. THE FEDERAL HEALTHCARE PROGRAMS

17. Medicaid and Medicare were created to provide access to healthcare for elderly, indigent or disabled residents of the United States.

A. <u>The Medicaid Program</u>

18. Medicaid is a joint federal-state program that provides health care benefits for certain groups, primarily the poor and disabled.

19. The federal Medicaid statute sets forth the minimum requirements for state Medicaid programs to qualify for federal funding. 42 U.S.C. § 1396a.

20. The federal portion of states' Medicaid payments, known as the Federal Medical Assistance Percentage ("FMAP"), is based on a state's per capita income compared to the national average. 42 U.S.C. § 1396d(b). Among the states, the FMAP is at least 50%, and as high as 83%.

21. The Medicaid statute requires each participating state to implement a plan containing certain specified minimum criteria for coverage and payment of claims. 42 U.S.C. §§ 1396, 1396a(a)(13), 1396a(a)(30)(A).

22. The Medicaid programs of all states reimburse for prescription drugs.

23. The vast majority of states award contracts to private companies to evaluate and process Medicaid recipients' claims for payment. Typically, after processing the claims, these private companies then generate funding requests to the state Medicaid program, which in turn obtains federal funds from the United States.

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24. By becoming a participating supplier in Medicaid, suppliers agree to abide by all laws, regulations, and procedures applicable to that program, including those governing reimbursement.

B. The Medicare Program

25. In 1965, Congress enacted Title XVIII of the Social Security Act, known as the Medicare program, to pay for the costs of certain healthcare services and items. Entitlement to Medicare is based on age, disability or affliction with end-stage renal disease. 42 U.S.C. §§ 426-426a, 1395o.

26. HHS is responsible for the administration and supervision of the Medicare program. CMS is an agency of HHS and directly administers the Medicare program. The Medicare program has several parts, including Medicare Part B ("Supplementary Medical Insurance for the Aged and Disabled"), which covers physician services, as well as durable medical equipment ("DME") and certain drug products and supplies. 42 U.S.C. § 1395k; 42 C.F.R. § 410.10.

27. Medicare Part B generally covers drugs which are provided either: (a) incident to a physician's service and cannot usually be self-administered (42 C.F.R. § 410.26 (*e.g.*, certain oncology drugs)); or (b) in conjunction with the medical necessity of an infusion pump or nebulizer or other DME device payable under Medicare's DME benefit. 42 C.F.R. §§ 405.517, 414.701.

28. During the relevant time period, CMS contracted with private insurance carriers ("Contractors") to administer and pay Part B claims from the Medicare Trust Fund. 42 U.S.C. § 1395u. In this capacity, the Contractors act on behalf of CMS. 42 C.F.R. § 421.5(b).

29. Contractors receive, process and pay claims under Medicare Part B for drugs from various Medicare providers and suppliers. Typically, once a contractor approves a claim, the contractor then submits a payment request to a Medicare bank account funded by federal funds.

C. <u>Drug Reimbursement Under Medicaid and Medicare</u>

30. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-97, requires pharmaceutical companies to submit to the Food and Drug Administration ("FDA") a listing of every drug product in commercial distribution. 21 U.S.C. § 355. The FDA provides for the assignment to each listed drug product of a unique 11-digit, 3-segment number, known as the National Drug Code ("NDC"). FDA has assigned approximately 170,000 NDCs to drug products. The drugs and corresponding NDCs at issue in this case are listed below:

DRUG	**NDC#**
Sodium Chloride Injection	00074196607
Water for Injection 30 ml	00074397703
Vancomycin HCl 500 mg	00074433201
Water for Injection 10 ml	00074488710
Water for Injection 20 ml	00074488720
Sterile Water for Injection	00074488750
Sodium Chloride Injection	00074488810
Sodium Chloride Injection	00074488820
Sodium Chloride Irrigation	00074613802
Sodium Chloride Irrigation	00074613803
Sodium Chloride Irrigation	00074613822
Sterile Water for Irrigation	00074613902
Sterile Water for Irrigation	00074613903

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Sterile Water for Irrigation	00074613922
Vancomycin HCl 5 gm	00074650901
Vancomycin HCl 1 gm	00074653301
Vancomycin HCL 500 mg Add-Vantage	00074653401
Vancomycin HCl 1 gm Add-Vantage	00074653501
5% Dextrose in Water 50 ml	00074710013
5% Dextrose in Water 100 ml	00074710023
Sodium Chloride Injection	00074710102
Sodium Chloride 0.9% 50ml	00074710113
Sodium Chloride 0.9% 100 ml	00074710123
Dextrose Injection	00074712007
Sodium Chloride Irrigation	00074713809
Sterile Water for Irrigation	00074713909
Dextrose 5%/ Kcl/NaCl 1000 ml	00074790209
Dextrose Injection	00074792202
5% Dextrose in Water 500 ml	00074792203
5% Dextrose in Water1000 ml	00074792209
Dextrose Injection	00074792336
Dextrose Injection	00074792337
Dextrose 5% and 0.225% NaCL Injection	00074792409
Dextrose 5% and 0.225% NaCL Injection	00074792609
5% Dextrose/ NaCl 0.9% 1000 ml	00074794109
Sodium Chloride Irrigation	00074797205
Sterile Water for Irrigation	00074797305
Sodium Chloride 0.9% 250 ml	00074798302
Sodium Chloride 0.9% 500 ml	00074798303
Sodium Chloride 0.9% 1000 ml	00074798309
Sodium Chloride Injection	00074798436
Sodium Chloride Injection	00074798437
Sodium Chloride Injection	00074798509
Water for Injection1000 ml	00074799009
Acyclovir Sodium 500 mg	00074442701
Acyclovir Sodium 1 gm	00074445201

31. Drug manufacturers, such as Abbott, have not typically submitted claims for reimbursement to federal health care programs. Instead, Abbott marketed its products to its Customers, who then purchased the products either directly or through wholesalers based on a price the Customers negotiated with Abbott. In addition to using wholesalers, Customers also

purchased Abbott products through group purchasing organizations ("GPO"), who negotiated prices on behalf of Abbott's Customers. However, as described in ¶¶ 111-138 below, Abbott also had a business unit that, among other activities, operated home infusion pharmacies and actually submitted reimbursement claims for drugs on behalf of various clients.

32. Abbott's Customers then submitted claims for payment for Abbott products to Medicare and Medicaid after dispensing or administering Abbott drugs. Medicare and Medicaid reimbursed some of the claims submitted by Abbott's home infusion pharmacies. In other instances, Abbott administered reimbursement claims for certain home infusion clients and collected portions of those clients' Medicare and Medicaid reimbursements as compensation for those services.

33. For the most part, in the Medicaid program, claims submitted by retail pharmacies are processed and tracked using the NDC of the drug.

34. The Medicare program generally uses the Healthcare Common Procedural Coding System ("HCPCS") to reimburse for drugs. The HCPCS utilize 5-digit alphanumeric codes to identify and bill for medical products and supplies. The codes at issue here are listed below:

HCPCS	**Description**
J2912	Sodium Chloride, .9 percent, per 2 ml
J3370	Vancomycin HCl, 500 mg
J7030	Normal Saline Solution, 1000 cc
J7040	Normal Saline Solution, 500 ml
J7042	5 percent Dextrose/Normal Saline Solution, 500 ml
J7050	Normal Saline Solution, 250 cc
J7051	Sterile Saline or Water, up to 250 cc
J7060	5 percent Dextrose/Water, 500 ml
J7070	D-5-W, 1000 cc
J7110	Dextran 75, 1000 ml
J7130	Hypertonic Saline Solution, 50 or 100 mEq, 20 cc vial

35. During the relevant period, Abbott usually reported prices to various price publishers and services on an annual basis. The price publishers used the information to publish pricing compendia.

36. The reimbursement amounts for claims submitted by Abbott or Abbott's Customers for the drugs at issue in this Complaint were directly influenced by Abbott's false price representations. The information contained in the published pricing compendia was used by most third party payor insurance companies, including the Medicare and Medicaid programs, in determining the reimbursement rates for prescription drugs. Abbott documents show that Abbott knew of the impact of its price representations on government reimbursement on claims submitted by its Customers for its drugs. Abbott documents also show that the company actively marketed the government-funded profits or "spreads" on its drugs created by its false price representations.

37. No governmental payor knew of or sanctioned Abbott's conduct as set forth in this Complaint, i.e., its deliberate manipulation of its published prices for certain of its products to induce its Customers to purchase those products.

D. <u>Medicaid Reimbursement Formulas</u>

38. When reimbursing for drugs, the State Medicaid programs' goal has been to pay an amount which, in the aggregate, reflects the lower of (1) the estimated acquisition cost ("EAC") of covered drugs, plus a reasonable dispensing fee, or (2) a provider's usual and customary charges to the general public. To determine the EAC for a covered drug, State

Medicaid programs are required to develop reimbursement formulas that must be approved by the Secretary of HHS. 42 C.F.R. §§ 447.331, 447.332, and 447.333 (2005).

39. While the specific reimbursement formulas vary from state to state, the various State Medicaid programs have generally reimbursed for each drug based on the lowest of (a) the EAC as set by the states, (b) the maximum allowable cost ("MAC") set by the state Pharmaceutical Reimbursement Boards, or (c) the providers' usual and customary charge. For multiple source drugs subject to a federal upper limit, states must in the aggregate not pay more than those limits. 42 C.F.R. §§ 447.331, 447.332 and 447.333 (2005).

40. The states' methodology for arriving at EAC includes:

A. discounting a percentage off of the Average Wholesale Price ("AWP");

B. adding a percentage to the Wholesale Acquisition Cost ("WAC") ; and/or,

C. requiring the drug companies to certify prices directly in writing to the Medicaid program in response to state requests for particular pricing information.

41. AWP is used to refer to the price at which a pharmaceutical firm or a wholesaler sells a drug to a retail Customer who then administers it to a patient. WAC is used to refer to the price at which a pharmaceutical firm typically sells a drug to wholesalers who would then resell it to a retail Customer.

42. While the majority of states use published AWPs to calculate reimbursement, approximately six states (Alabama, Florida, Maryland, Massachusetts, Rhode Island and Texas) have used the wholesale acquisition cost ("WAC") to set the EAC.

43. The AWPs and WACs relied upon by the State Medicaid programs have generally been those published by (1) Thomson Publishing, publisher of the *Red Book* and various other price publications, (2) First Databank, publisher of the *Blue Book* and other electronic price publications; or (3) Medi-Span, Inc., publisher of an electronic or automated price service and the Hospital Formulary Pricing Guide. Thompson Publishing, First Databank and Medi-Span, Inc. are hereafter referred to as the "Publishers" and their various publications and data services are hereinafter referred to as "Price Publications."

44. In addition to relying on the manufacturers' reported prices as published in the Price Publications, some State Medicaid programs also received price representations directly from manufacturers, and relied on these representations to confirm the accuracy of the figures they use to determine state reimbursement amounts. For example, the State of Texas required drug companies to submit their prices directly to the Texas Medicaid program in a signed certification attesting to the accuracy of the price information.

E. <u>Medicare Reimbursement Formulas</u>

45. From 1992 through 1997, Medicare based its reimbursement for multi-source generic drugs, the drugs at issue here, at the lower of the EAC or the median AWP of all generic forms of a drug. 42 C.F.R. § 405.517 (1992-1998). In general, Medicare relied on median AWPs to set reimbursement rates.

46. From January 1, 1998, until December 31, 1998, Medicare based its reimbursement for all generic forms of a drug at 95% of the median AWP for the drug. Balanced Budget Act of 1997, 42 U.S.C. § 1395u(o); 42 C.F.R. § 405.517 (1998).

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47. From 1999 through 2004, Medicare based its reimbursement for all generic forms of a drug at the lower of (1) 95% of the median published AWP for the drug; or (2) the AWP of the least expensive brand-name drug. 42 U.S.C. § 1395u(o); 42 C.F.R. § 405.517 (1999-2004).

48. After the reimbursement amount is calculated, Medicare pays 80 percent and the Medicare beneficiary is responsible for the remaining 20 percent co-payment. If the Medicare beneficiary is also a Medicaid recipient, the Medicaid program generally pays the 20 percent Medicare co-payment.

49. Medicare generally relied upon the AWPs published by Thomson Publishing in its annual national compendium known as the *Drug Topics Red Book* ("*Red Book*"), as well as *Red Book* monthly updates to set reimbursement rates for covered drugs.

VII. ABBOTT'S SCHEME

50. From at least on or before January 1, 1991, and continuing through 2001, Abbott defrauded the United States by knowingly causing the Medicare and Medicaid programs to pay false or fraudulent claims for dextrose solutions, sodium chloride solutions, sterile water, Vancomycin and Acyclovir Sodium.

51. The specific dextrose solutions, sodium chloride solutions, sterile water, Vancomycin and Acyclovir Sodium products at issue herein are identified by NDC or HCPCS Code in ¶¶ 30 and 34 above and are hereinafter referred to jointly as the "Drugs."

52. Dextrose solutions, sodium chloride solutions, and sterile water are generic, water-based solutions used to facilitate the intravenous infusion of other drugs and for fluid replacement, and are commonly referred to as large volume parenterals ("LVPs").

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53. Vancomycin is a powerful, intravenous antibiotic that Abbott has sold as a generic drug since 1988.

54. Acyclovir Sodium ("Acyclovir") is an antiviral drug used to treat several opportunistic viral infections, some of which are associated with HIV/AIDS.

55. Abbott marketed and sold its products, including the Drugs, to Customers.

56. The Customers purchased the products either directly from Abbott, through a GPO contract or through wholesalers.

57. The amount paid by a Customer was typically based on a price negotiated with Abbott or the GPO.

58. Regardless of the method of purchase, Abbott's Customers submitted claims for payment to Medicare and Medicaid when an Abbott product was administered to a program beneficiary. The claims submitted by Abbott's Customers were paid at amounts directly influenced by Abbott's false and fraudulent prices.

59. Abbott routinely disseminated false pricing information for the Drugs to the Pricing Publications. Abbott employees typically reported the false and fraudulent prices to the Price Publications annually, although they sometimes did so more often. On most occasions, Abbott reported inflated "List Prices" or "Direct Prices" (both referred to hereinafter as LP), WACs and/or AWPs. A LP is supposed to reflect the price paid by a Customer that buys drugs directly from Abbott and not through a wholesaler.

60. When Abbott reported a LP, some Price Publications (*e.g.*, *Blue Book*, which provided pricing information for the vast majority of the state Medicaid programs) calculated

Abbott's AWPs by applying a markup – usually 18.75% – to the LPs. Abbott was aware of how the Price Publications set its AWPs and knew (1) that the markup remained constant and (2) that its LPs ultimately controlled the AWP reported by the Price Publications for many of its products. Abbott reported WACs for several of its drugs as well, but during the time period covered by the Complaint, the Price Publications used Abbott's LPs (plus the standard markup) to set the AWPs used by the Medicaid and Medicare programs.

61. In some circumstances, Abbott itself calculated and supplied the AWP which it sought to have published.

62. For example, in a January 16, 1996 letter from Abbott's Reimbursement Manager to Medi-Span, Abbott directly reported AWPs for two of its products.

63. Abbott documents also confirm its knowledge that the LPs it reported directly impacted the AWP. In a March 20, 1995 e-mail between Abbott employees regarding the reporting of new Vancomycin LPs, one employee notes, "Please notify Red Book and Medi-Span of these changes ASAP. They are the sources for creating the AWP that is important to [Abbott's] Alternate Site [sales division]."

64. Abbott also submitted false and fraudulent prices directly to state Medicaid programs. In an October 1, 1997, Abbott "Medicaid Coordinator" Tena Brown represented in a letter to the State of Texas Medicaid Program that the price on Abbott's Vancomycin 1 GM Fliptop vial- sterile, NDC 00074-6533-01 ("Vancomycin 1 GM FTV") was $583.70 for a package of 10, or $58.37 a unit. That led the Texas Medicaid program to set reimbursement for

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Vancomycin 1 GM FTV at that price ($58.37 a unit). At the time, Abbott sold Vancomycin 1 GM FTV to certain Customers for $5.53 per unit, through a GPO called Oncology Solutions.

65. With extremely few exceptions, Abbott reported increasingly higher prices for the Drugs from at least on or before January 1, 1991 through 2001. At the same time, the prices Abbott actually charged to its Customers decreased or remained the same.

66. Abbott knew that the prices which it reported to the Price Publications directly affected reimbursement amounts paid by the Medicaid and Medicare programs. As Abbott's Manager for Reimbursement noted in an April 26, 1995 memorandum, "[h]aving a published [LP] that is high allows a provider to bill at that list price." The false or fraudulent prices Abbott reported to the Price Publications inflated government reimbursement amounts on claims submitted by Abbott's Customers for the Drugs. A chart setting out some examples showing the difference between the prices at which Abbott actually sold its drugs and the false prices reported by Abbott is attached hereto as **Exhibit 1**.

67. Abbott manipulated its LPs, AWPs and WACs to induce its Customers to purchase Abbott's products, including the Drugs, by marketing the huge profits that would result to its Customers.

68. Abbott was well aware of how the Government used its pricing information to reimburse Abbott products. For example, Abbott organized an internal entity known as the "Medicare Working Group." The group (1) was organized by high level Abbott executives, (2) involved representatives responsible for reimbursement issues from all major Abbott divisions, and (3) discussed and organized efforts to influence government reimbursement for drugs.

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69. Documents from the Medicare Working Group establish that Abbott knew that AWP is based upon Abbott's reported price plus, according to the Medicare Working Group documents, "a mark-up of 15-20%." Minutes from a January 21, 1997 meeting note that this AWP based on Abbott's reported prices is subsequently reported in "the Red Book, Blue Book and Medispan Book and is used by Medicare, Medicaid and Commercial insurance carriers to determine reimbursement levels."

70. Neither the Medicaid nor the Medicare programs knew of or sanctioned Abbott's conduct as set forth in this Complaint, *i.e.*, the deliberate manipulation of its published prices to induce its Customers to purchase the Drugs. Abbott never disclosed the price reporting practices for the Drugs identified in this Complaint to the Medicaid or Medicare programs.

A. <u>Vancomycin</u>

71. Abbott first introduced its generic Vancomycin in 1988. Abbott's scheme to defraud the United States by causing inflated Vancomycin reimbursements ran from approximately 1989 through 2001. Over that time period, Medicare and Medicaid paid in excess of $75 million for Abbott's Vancomycin.

72. During that time period, Abbott reported increasingly higher LPs and AWPs for Vancomycin to the Price Publications while the actual contract prices at which Abbott sold Vancomycin to its Customers decreased significantly.

73. Abbott sold its Vancomycin in several doses and forms. The Vancomycin 1 GM FTV was the most common dose of Vancomycin reimbursed by Medicare and Medicaid.

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Abbott's false and fraudulent price reporting on its Vancomycin 1 GM FTV represents how Abbott reported false and fraudulent prices on its other Vancomycin products.

74. When Abbott first introduced its Vancomycin 1 GM FTV in 1988, the published per unit AWP was $25.20. By early 2001, Abbott reported false prices that drove the AWP for Vancomycin 1 GM FTV to $76.42. At the same time, the price at which Abbott's Vancomycin was widely available to purchasers decreased to under $4.00 by early 2001; the difference (and potential profit) between the reported price and the actual selling price for Vancomycin 1 GM FTV was as great as $72.42 a dose, or more than 18 times the actual price at which Abbott sold Vancomycin 1GM FTV.

75. Abbott fully controlled and manipulated the AWPs for Vancomycin 1 GM FTV to boost its Vancomycin sales at the expense of third party payors, including Medicare and Medicaid.

76. Abbott's manipulation of its reported Vancomycin prices between 1989 and 2001 created spreads sufficient to induce increased sales of that drug. Internal memoranda from senior Abbott sales staff reveal that Abbott actively knew about and marketed the large spreads on several of its drugs, including Vancomycin. Those efforts proved successful; the percentage of Abbott's Vancomycin sales reimbursed by Medicaid increased from less than 10% in 1991 to approximately 70% in 2000.

77. Abbott's reporting of Vancomycin prices in 1995 exemplifies the manner in which Abbott manipulated the price of Vancomycin to maintain and grow its market share. In March 1995, Abbott temporarily reported dramatically lower LPs and AWPs for Vancomycin.

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Prior to the March 1995 LP/AWP price change, the Price Publications listed a per unit LP of $50.90 for Abbott's Vancomycin 1 GM FTV, and a per unit AWP of $60.44 for that drug.

78. In late March 1995, Abbott reported a new LP of $15.00 for a unit of Vancomycin 1 GM FTV. Based on this new information from Abbott, the Price Publications published revised per unit prices for Vancomycin 1 GM FTV. They reported a LP of $15.00 and an AWP of $17.81.

79. Abbott received numerous complaints from Customers over the resulting decrease in the spread. Abbott deliberated internally on whether and by how much Abbott should again increase its spread so that it could reestablish the inducement that had come to be expected by its Customers. Abbott documents show Abbott's pricing personnel carefully considering the additional profits they could generate for Abbott's Customers if they artificially re-inflated the reported prices for Vancomycin 1 GM FTV at various levels.

80. Abbott subsequently reversed its earlier decision to lower its reported prices and instead raised its reported Vancomycin prices. In early May 1995, Abbott reported a new per unit LP for its Vancomycin 1 GM FTV of $32.95. The revised AWP for Abbott's Vancomycin 1 GM FTV became $39.13 (once the Price Publication applied the standard markup).

81. That reported price increase proved insufficient. Later that same month (May 1995), Abbott reported yet another set of prices for Vancomycin. The LP Abbott reported for its Vancomycin 1 GM FTV rose to $52.94 and its AWP rose to $62.86 (once the Price Publication applied the standard markup).

82. Thereafter, Abbott reported higher Vancomycin LPs and AWPs to the Publishers each year, despite decreases in its actual prices to Customers for Vancomycin over that same period. The AWP for Abbott's Vancomycin 1 GM FTV peaked at $76.42 per unit in early 2001 at the same time that the actual sales price was less than $4 per unit.

83. The false prices reported by Abbott directly impacted the amount Medicaid and Medicare reimbursed for Vancomycin. For example, in 1999 Abbott's Vancomycin 1 GM FTV was widely available for approximately $4.75 a unit. Yet, Abbott reported a per-unit Vancomycin LP in 1999 – which served as the baseline for determining the AWP – to First DataBank of $64.35. As a result, the 1999 AWP for Vancomycin 1 GM FTV was set at $76.42.

84. New York State's Medicaid program relied on the First DataBank prices to set its reimbursement rate for the Vancomycin 1 GM FTV. New York State's Medicaid reimbursement rate for the Vancomycin 1 GM FTV in 1999 was $68.77; the AWP for Vancomycin 1 GM FTV was $76.42 at the time. New York's reimbursement for Vancomycin 1 GM FTV was AWP minus 10%, a reimbursement formula generally similar to those of other states. Abbott's false price representations created a profit spread of approximately $64.02 for Abbott's Customers, on a drug that Abbott sold to those same Customers for approximately $4.75 a unit. The spread between the New York state Medicaid reimbursement for Vancomycin 1 GM FTV – directly influenced by Abbott's false price reporting – and the actual acquisition cost was 1,348%. The profit to Abbott's Customers was 13.5 times the typical acquisition cost for the drug.

85. Abbott's practice of price manipulation continued into early 2001. At that time, Abbott reported new, lower WACs to the Price Publications for many of its drugs, including

Vancomycin, without also reporting new LPs or AWPs. At the time Abbott submitted the new prices in early 2001, it had been under investigation by the Government for pricing fraud. In addition, members of the House Ways and Means Committee accused Abbott of engaging in price reporting misconduct that threatened public safety in the fall of 2000; the Centers for Disease Control had expressed concerns that over-prescription of Vancomycin could lead to the growth in the population of Vancomycin-resistant bacteria. Also, in October 2001, an Abbott joint venture, TAP Pharmaceuticals, Inc. paid $875 million to the Government to resolve its criminal responsibility and civil liability for fraudulent pricing and kickbacks in connection with the marketing of a drug called Lupron. When Abbott submitted reduced WACs, First DataBank changed the way it calculated Abbott's AWP. First Databank personnel set new AWPs for Abbott products by applying a 25% markup to the newly supplied WACs instead of setting Abbott's AWPs by applying a 18.75% markup to Abbott's still inflated LPs. Abbott tried to convince First DataBank personnel not to set Abbott's AWP by reference to these new, lower WACs; Abbott wanted First DataBank to continue to use Abbott's then still inflated LPs to maintain its inflated AWPs. First DataBank refused Abbott's request. Ultimately, Abbott reduced its LPs and WACs to reflect the average sales price for the Drugs on April 30, 2001.

86. The switch to using the lowered WACs drastically dropped Abbott's reported AWPs in 2001. For Abbott's Vancomycin 1 GM FTV, the AWP dropped from $76.42 per unit in early 2001 (when AWP was determined using the inflated LPs) to $17.72 per unit in 2001 (when AWP was set using the revised, lowered WACs). By 2002, the AWP for this product was down to $6.06 a unit.

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87. As a result of the drop in AWP, the spread on the reimbursement by Medicare and Medicaid was reduced from $60-$70 a unit to approximately $2.00 a unit.

88. Abbott's Customers recognized that Abbott was responsible for creating and maintaining the spread. Numerous Customers complained to Abbott or the group purchasing organizations (GPOs) who negotiated prices on behalf of Abbott's Customers. A large Customer of Abbott went so far as to demand restitution for the almost $10.5 million in lost profits due to the decrease in spread resulting from Abbott's 2001 submission of lowered prices to the reporting agencies.

89. Internal memoranda from senior Abbott sales staff reveal that Abbott actively knew about and marketed the large spreads on several of its drugs, including Vancomycin, as an inducement to purchase Abbott's drugs.

90. Abbott's share of the Medicaid market has dropped steadily since the more accurate prices started being published in 2001 and thereafter went from approximately 70% in early 2001 to approximately 20% in 2004.

B. <u>Large Volume Parenterals</u>

91. In addition to false price reporting for Vancomycin, Abbott engaged in similar conduct with respect to its LVPs.

92. LVPs are essentially sterile water, usually mixed with either salt (sodium chloride) or sugar (dextrose). LVPs are cheap to produce and are sold at very low prices.

93. One of the most commonly utilized Abbott LVPs was 5% Dextrose in Water, 500 ml, NDC # 00074-7922-03 ("5% Dextrose 500 ml").

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94. In 1993, Abbott's 5% Dextrose 500 ml could be widely purchased for as little as $1.80 for a 500ml bag.

95. The Red Book AWP for 5% Dextrose 500 ml in 1993 was $8.72.

96. Two years later, in 1995, the price for Abbott's 5% Dextrose 500ml was widely available for even less; one wholesaler was selling it at $1.50 for a 500 ml bag.

97. During the same two year period from 1993 to 1995 that the actual prices dropped, Abbott twice reported higher prices to the Price Publications for 5% Dextrose 500 ml. The AWP – based on Abbott's representations – increased by 5% in 1994 to $9.16 and was increased by an additional 3% in 1995 to $9.43.

98. Thus, while Abbott's price to the wholesaler dropped by 20% between 1993 and 1995 (from $1.80 to $1.50), Abbott caused its AWP to increase by 8%. By 1995, the spread between the AWP and the resale price of that wholesaler was 628%.

99. Abbott sold these products directly to Customers at prices comparable to those offered by the wholesaler.

100. Abbott continued to report increasing prices for 5% Dextrose 500 ml after 1995. By reporting increasingly inflated LPs, Abbott caused the Red Book AWP for 5% Dextrose in Water, 500 ml, NDC # 00074-7922-03 to increase in 1996 to $9.71, in 1997 to $10.20, in 1998 to $10.71, in 1999 to $11.25 and in 2000 to $11.80. Medicaid and Medicare used these reported prices to set their reimbursement levels. At the same time, Abbott regularly sold the product to its Customers for $1.50 or less per bag of the water-based solution.

101. Abbott's reporting of increasingly false and fraudulent prices for its 5% Dextrose 500ml reflects the manner in which Abbott implemented its scheme for all of the LVPs during the relevant time period. Abbott engaged in identical conduct with respect to the "prices" and marketing of the other LVP products and package sizes identified by NDC and HCPCS code in ¶¶ 30, 34 of this Complaint.

102. Abbott used the false and fraudulent prices Abbott reported to the Price Publications for these water solutions to manipulate reimbursement; the reported prices did not reflect the actual prices Abbott was charging to its Customers.

103. Due to Abbott's conduct, Abbott's Customers submitted inflated claims to Medicare and Medicaid and received millions of dollars in inflated reimbursement for these water and water-based solutions. Abbott profited off the scheme by increasing its sales volume and profits. Medicare and Medicaid have paid Abbott's Customers in excess of $100 million for Abbott's LVPs when the typical acquisition costs for those Customers were a fraction of that amount.

C. <u>Acyclovir Sodium</u>

104. Acyclovir Sodium (Acyclovir) is an antiviral drug used to treat several infections. The brand version, called Zovirax, was originally manufactured by Glaxo Welcome, Inc. Abbott began selling its generic version of the drug on April 22, 1997.

105. At the time Abbott launched its versions of Acyclovir in 1997, it reported a LP of $80.00 for the 500MG Dose of its generic version of Acyclovir (NDC#00074-4427-01). The

1997 Blue Book AWP for Abbott's Acyclovir Sodium 500MG was $95.00 (reflecting the standard price publication mark up on Abbott products of 18.75%).

106. By 1999, Abbott had raised its reported LP for its Acyclovir Sodium 500MG to $88.20; the AWP for that dose of Abbott's Acyclovir Sodium had risen to $104.74.

107. Yet, competition among manufacturers of Acyclovir drove the contract prices for the drug down sharply. In 1997, Abbott's Acyclovir Sodium 500MG could be purchased for $30.00. By 2000, the typical purchase price for Abbott's Acyclovir Sodium 500MG had eroded to around $11.

108. Thus, the spread on Abbott's Acyclovir went from as much as 316% at product launch in 1997 to as much as 960% by 2000.

109. Abbott actively marketed the reimbursement spread on Acyclovir to Customers, including Ven-A-Care, the relator in this matter. Ven-A-Care operated a home infusion pharmacy that largely serviced HIV/AIDS patients. On or around May 30, 1997, an Abbott national account manager directly marketed the spread on its Acyclovir Sodium to Ven-A-Care. That national account manager sent documents reflecting the spread on Abbott's Acyclovir and had conversations with Ven-A-Care where he explicitly marketed the spreads on Abbott's Acyclovir products.

110. On April 30, 2001, Abbott reported new LPs and WACs for its Acyclovir products. As noted above, the price reporting compendia changed the method it used to calculate Abbott's AWP. First Databank began using Abbott's WAC and applying a 25% markup. The LP for Abbott's Acyclovir Sodium 500MG dropped from $88.20 to $4.00; the WAC dropped to

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$3.81. The per unit AWP – based on a 25% markup from the $3.81 WAC – for Abbott's Acyclovir Sodium 500MG dropped from $104.74 to $4.76. The revised LP, WAC and AWP was in keeping with the actual contract price for Abbott's Acyclovir Sodium 500MG, which by mid-2001 was around $4.00 a unit.

D. Abbott's Home Infusion Pharmacies, Home Infusion Partnerships and Consignment Arrangements.

1. Home Infusion Pharmacies

111. From approximately 1982 until, upon information and belief, 2003, Abbott owned and operated its own Home Infusion Pharmacies ("Abbott HI Pharmacies") as part of its Hospital Products Division's ("HPD"), Alternate Site Home Infusion Department.

112. Abbott's HI Pharmacies were located at various times in Atlanta, Georgia, Chicago, Illinois, Los Angeles, California, and in New Jersey. At some point in that period, the Abbott HI Pharmacy in Atlanta Georgia closed.

113. Abbott billed Medicare and Medicaid for products and services dispensed by the Abbott HI Pharmacies using Abbott's EIN number and Abbott's own Medicare and Medicaid provider codes.

114. Abbott HI Pharmacies stocked and dispensed Abbott products, including, without limitation, products identified in this Amended Complaint in ¶ 30, as well as other products produced and sold by Abbott and other manufacturers. Upon information and belief, Abbott stocked its own products at or near the manufacturing costs for those products. Upon information and belief, Abbott was able to acquire other manufacturers' drugs at reduced, contracted prices.

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115. The Abbott HI Pharmacies billed Medicare and Medicaid through the "Abbott Reimbursement Department" in Abbott's HPD Alternate Site Home Infusion Department.

116. Each of the Abbott HI Pharmacies would operate as follows:

A. The Abbott HI Pharmacies would receive patient prescriptions from physicians, hospitals, outpatient clinics or other care providers.

B. Abbott's Reimbursement Department would ascertain whether the referred patient was eligible for reimbursement for his or her prescription costs through Medicare, Medicaid or a third party insurer.

C. Upon receipt of the prescriptions, the Abbott HI Pharmacies would fill the prescription and would, upon information and belief, at times provide pharmacist services.

D. After the prescriptions were filled by an Abbott HI Pharmacy, the Abbott Reimbursement Department would bill either Medicare, Medicaid or a third-party insurer for the dispensed drug or product, depending upon patient eligibility.

E. For those patients covered under Medicare or Medicaid, a reimbursement clerk in the Abbott Reimbursement Department would complete a paper or, at a later point, an electronic, Medicare HCFA 1500 form seeking reimbursement from Medicare or a Medicaid reimbursement form.

117. The HCFA 1500 forms or Medicaid reimbursement forms submitted by the Abbott Reimbursement Department would reflect Abbott's EIN number and provider number as the entity to be reimbursed.

118. Depending upon the drug and the state program, Medicaid would typically pay to Abbott the AWP or WAC-based reimbursement for drug or product for which Abbott's HI Pharmacy billed. Medicare would typically pay to Abbott the AWP-based reimbursement for drug or product for which Abbott's HI Pharmacy billed. Abbott would retain for itself as a profit the difference between the cost of the drug or product to Abbott and the amount of the AWP-based reimbursement ("Abbott HI Pharmacy spread").

119. Upon information and belief, Abbott did not disclose the Abbott HI Pharmacy spreads to the Medicare or Medicaid programs when it submitted reimbursement forms.

120. The amounts Abbott HI Pharmacies were reimbursed by Medicare and Medicaid regularly exceeded the cost to Abbott in stocking and dispensing the drugs and products dispensed by the Abbott HI Pharmacies – including its own.

121. In the case of the Abbott Drugs identified in this Complaint, Abbott's HI Pharmacies were reimbursed inflated amounts for any claims they submitted for those Drugs due to Abbott's fraudulent price reporting scheme.

2. <u>Abbott's Home Infusion Partnerships and Consignment Arrangements</u>

122. From approximately 1984 until, upon information and belief, 2003, Abbott HPD's Alternate Site Home Infusion Department entered into home infusion partnerships ("HI Partnerships") with various hospitals, care facilities and other medical entities. These HI Partnerships permitted Abbott's home infusion partners ("HI Partners") or – in some instances Abbott – to bill government health programs on behalf of its HI Partners for the Drugs identified in ¶ 30 at inflated reimbursement levels.

123. Abbott had at least 20 to 25 home infusion partners ("HI Partners") in these partnerships including, but not limited to:[3] University of Michigan's HomeMed, Children's Memorial Hospital of Chicago, Care Partners, Baylor, Harris Methodist, UniHealth, Intermountain, Cedars Sinai, University of Virginia, Seattle Children's Hospital, Cleveland Clinic, and University Hospitals of Cleveland.

124. Abbott entered into standard partnership agreements with the HI Partners and others. Under the terms of the partnership agreements, Abbott would:

A. Provide its HI Partners Abbott drugs and products free of charge on a consignment basis, including but not limited to, the Drugs identified in ¶ 30 of this Complaint;

B. Provide its HI Partners agreed upon services, including, on occasion, "reimbursement services;" and

C. Add the HI Partner to a group purchasing organization of which Abbott was a member, so that the HI Partner, or Abbott on behalf of the HI Partner, could purchase drugs and products that Abbott did not manufacture or sell ("Other Non-Abbott products") at a substantially reduced contract rate.

125. The HI Partner would dispense the drugs or products from its pharmacy. If the drug or product was an Abbott product, that product would be a consigned product that the HI

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[3] These HI partners are described herein as identified by an Abbott witness. For some of these HI partners, the witness did not provide full and complete name information.

Partner would not pay for on an individual basis, or at any time prior to when the HI Partner billed Medicare or Medicaid.

126. As part of its "reimbursement" services for some HI Partners, Abbott's Reimbursement Department would submit claims to Medicare, Medicaid and other third party payors for drugs, medical devices and medical services on the HI Partner's behalf, using the HI Partner's EIN number and Medicare and Medicaid provider codes.

127. For patients covered under Medicare or Medicaid, an Abbott reimbursement clerk in the Reimbursement Department would complete a paper or, at a later point, electronic, Medicare HCFA 1500 form seeking reimbursement from Medicare, or the appropriate Medicaid reimbursement form seeking reimbursement from a State Medicaid program on behalf of the HI Partner.

128. Abbott provided reimbursement services to, among others, Care Partners, University of Michigan, Children's Hospital and the University of Virginia.

129. If Abbott was providing reimbursement services to an HI Partner, Abbott's Reimbursement Department would collect reimbursements from Medicare, Medicaid and other third party payors for claims submitted on behalf of that HI Partner. Those reimbursement amounts were collected in lock box bank accounts that, upon information and belief, were maintained in the name of the HI Partner or Abbott.

130. Upon information and belief, Abbott would never bill the HI Partners for the drugs and products it consigned to them, and would never expect payment for them. Abbott's payment for the consigned Abbott drugs would be some percentage of the HI Partner's entire pool

of collections from Medicare, Medicaid and third party payors, regardless of whether it was Abbott or the HI Partner that submitted the claim.

131. Under the Consignment Partnership Agreements, the HI Partners would never pay Abbott individual amounts for the drugs or products consigned to the HI Partner. The Medicare and Medicaid drug reimbursements were used by Abbott to compensate it for billing and consulting services not related to the provision of patient care.

132. For example, a December 1996 Consignment Partnership Agreement, required a HI Partner to pay Abbott 45.1 % of its gross revenue collections for all of its IVIG treatment, including any administration fee and/or any drug ingredient cost. Thus, Abbott would receive a percentage of any inflated reimbursement spreads for the Drugs identified in ¶ 30 of this Complaint that were provided to its HI Partners on consignment.

133. Abbott never disclosed to the Medicare or Medicaid programs that it was directly profiting from the reimbursement spreads in the above-described arrangement with the HI Partners.

134. If an HI Partner would not contract for reimbursement services, the HI Partner would submit the claims to Medicare and Medicaid and directly collect the reimbursements. However, Abbott would still consign its drugs and products to the HI Partner and still share in a percentage of the total collections collected by the HI Partner.

135. Several state Medicaid programs would reimburse for Abbott drugs covered by this arrangement at amounts tied to the AWPs or WACs for those drugs. Medicare also reimbursed for Abbott drugs covered by these arrangements at amounts tied to the AWPs for the

Abbott drugs. That amount would then be paid to the HI Partner, who in turn would provide a percentage share to Abbott of its entire collections as payment for various types of categories of services.

136. The cost to Abbott in stocking the HI Partner's warehouses with Abbott and non-Abbott drugs and products was far less than the amounts reimbursed by Medicare and Medicaid for those drugs and products.

137. Abbott did not disclose to the Medicare and Medicaid programs that the drugs and products it sought reimbursement for from Medicare or Medicaid actually cost Abbott far less to consign to the HI Partner than the ultimate Medicare or Medicaid reimbursement amount.

138. In the case of the Abbott Drugs identified in this Complaint, Abbott's percentage of HI Partner reimbursements Abbott that collected was improperly inflated due to Abbott's fraudulent price reporting scheme.

FIRST CAUSE OF ACTION

(False Claims Act: Presentation of False Claims)
(31 U.S.C. § 3729(a)(1))

139. Plaintiff repeats and realleges ¶¶ 1 through 138 as if fully set forth herein.

140. Abbott knowingly caused or caused to be presented false or fraudulent claims for payment or approval to the United States for the Drugs for reimbursement that were substantially higher than providers' actual acquisition costs for the Drugs and based on reported prices that were fraudulently and artificially manipulated by Abbott. Abbott knowingly used the spread as an unlawful inducement in violation of the federal anti-kickback statute, causing resulting false and fraudulent claims to be submitted.

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141. By virtue of the false or fraudulent claims that Abbott caused to be made, the United States has suffered damages and therefore is entitled to multiple damages under the False Claims Act, to be determined at trial, plus civil penalties of not less than $5,000 and up to $10,000 for each violation occurring before September 29, 1999, and not less than $5,500 and up to $11,000 for each violation occurring on or after September 29, 1999.

SECOND CAUSE OF ACTION

(False Claims Act: Making or Using False
Records or Statements to Cause Claims to be Paid)
(31 U.S.C. § 3729(a)(2))

142. Plaintiff repeats and realleges ¶¶ 1 through 138 as if fully set forth herein.

143. Abbott knowingly made, used, or caused to be made or used, false records or statements – *i.e.*, the false certifications and representations made or caused to be made by defendants to state Medicaid programs when seeking to ensure that the Medicaid programs would reimburse for the Drugs, and the false representations to the Publishers upon which Medicare and Medicaid relied – to cause false or fraudulent claims paid or approved by the United States.

144. By virtue of the false records or false statements made by Abbott, the United States suffered damages and therefore is entitled to treble damages under the False Claims Act, to be determined at trial, plus civil penalties of not less than $5,000 and up to $10,000 for each violation occurring before September 29, 1999, and not less than $5,500 and up to $11,000 for each violation occurring on or after September 29, 1999.

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THIRD CAUSE OF ACTION

(Unjust Enrichment)

145. Plaintiff repeats and realleges ¶¶ 1 through 138 as if fully set forth herein.

146. This is a claim for the recovery of monies by which Abbott has been unjustly enriched, including (1) profits earned by Abbott through its HI Pharmacies and Consignment Partnership Agreements and (2) profits from increased sales resulting from the illegal inducements that Abbott arranged to be paid to its Customers.

147. By obtaining monies as a result of its violations of federal and state law, Abbott was unjustly enriched, and is liable to account for and pay such amounts, which are to be determined at trial, to the United States.

148. By this claim, the United States requests a full accounting of all revenues (and interest thereon) and costs incurred by Abbott on sales to Customers to whom it arranged for unlawful inducements, and disgorgement of all profits earned and/or imposition of a constructive trust in favor of the United States on those profits.

FOURTH CAUSE OF ACTION

(Common Law Fraud)

149. Plaintiff repeats and realleges ¶¶ 1 through 138 as if fully set forth herein.

150. Abbott made material and false representations concerning the prices of the Drugs with knowledge of their falsity or reckless disregard for the truth, with the intention that the United States act upon the misrepresentations to its detriment. The United States acted in justifiable reliance upon Abbott's misrepresentations by making payments on the false claims.

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151. Had the true facts of Abbott's false price reporting as set forth in this Complaint been known to the United States, the United States would not have paid for Abbott products.

152. By reason of these payments, the United States has been damaged in an as yet undetermined amount.

PRAYER FOR RELIEF

WHEREFORE, the United States demands and prays that judgment be entered in its favor against Abbott, jointly and severally, as follows:

1. On the First and Second Causes of Action, for the amount of the United States' damages, trebled as required by law, and such civil penalties as are required by law, together with all such further relief as may be just and proper.

2. On the Third Cause of Action, for the damages sustained and/or amounts by which Abbott was unjustly enriched, including an accounting of all revenues unlawfully obtained by Abbott, the imposition of a constructive trust upon such revenues, and the disgorgement of the illegal profits obtained by Abbott, plus interest, costs, and expenses, and all such further relief as may be just and proper.

3. On the Fourth Cause of Action, for compensatory and punitive damages in an amount to be determined, together with costs and interest, and for all such further relief as may be just and proper.

DEMAND FOR JURY TRIAL

The United States demands a jury trial in this case.

For the United States of America,

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Dated: June 4, 2007

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CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above **UNITED STATES' FIRST AMENDED COMPLAINT** to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Mark A. Lavine

Dated: June 4, 2007 Mark A. Lavine